

# GLOBAL PHARMACEUTICAL PATENT LAW IN DEVELOPING COUNTRIES- AMENDING TRIPS TO PROMOTE ACCESS FOR ALL

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## I. INTRODUCTION

Eight thousand people die from AIDS in the developing world everyday due to the lack of access to essential medicines.<sup>1</sup> The main barrier to access is high drug prices.<sup>2</sup> Significant advances in medicine and technology have improved public health and extended overall life expectancy, but not for everyone due to lack of access resulting from exorbitant prices.<sup>3</sup> Despite government regulatory agencies and pharmaceutical research departments working together to develop safe and effective medicines at an increasing rate, access to these medicines has been limited.<sup>4</sup> Crucial new medicines for infectious diseases such as HIV-AIDS, Malaria, and Tuberculosis are priced out of the reach of the millions of people in the developing world, who gravely need them.<sup>5</sup> The inflated price of these vital medicines is due in part to global patent rules, which restrict the availability and access to affordable generic versions of life-saving patented medicines.<sup>6</sup> Developing country governments have attempted to improve access to essential medicines by taking various measures, which reduce the price of drugs, but they have

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<sup>1</sup> Ellen 't Hoen, *European Parliament Committee on International Trade Hearing on TRIPS and Access to Medicines*, Medecins Sans Frontieres (MSF) Access to Essential Medicines Campaign, Jan. 18, 2005, available at <http://www.accessmed-msf.org/documents/ETHatEPhearing.pdf> (last visited Apr. 10, 2005).

<sup>2</sup> *Id.* at 1.

<sup>3</sup> Jennifer Brant, *Robbing the Poor to Pay the Rich? How the United States Keeps Medicines From the World's Poorest*, Oxfam International Briefing Paper, vol. 56, Nov. 2003, available at [http://www.oxfam.org/eng/pdfs/pp031201\\_robbing\\_medicines\\_US.pdf](http://www.oxfam.org/eng/pdfs/pp031201_robbing_medicines_US.pdf) (last visited Apr. 10, 2005).

<sup>4</sup> Stephen Barnes, Note, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 913 (2003).

<sup>5</sup> Brant, *supra* note 3.

<sup>6</sup> *Id.*

faced extreme pressure from developed countries and from the multinational pharmaceutical industry based on the current system of global pharmaceutical patent protection.<sup>7</sup>

[Patents and] medicine are inextricably inter-linked. Patents are a monopoly. Drug companies possess separate monopolies over many life-saving and other drugs, including those that treat HIV-AIDS. As monopolists, these companies have no compunctions about fixing high prices for essential drugs. High prices create a clear divide between the rich who can afford the medicine and the poor who cannot.<sup>8</sup>

The major complaint concerning current international patent law is the imbalance between rights of the pharmaceutical companies and the lack of obligation to provide access to essential medicines.<sup>9</sup> Despite the assurance from the developed countries that the global patent system is a stimulant for pharmaceutical innovation, research, and development; in reality, this innovation, research, and development is almost exclusively confined to the private sector and areas of profitable return.<sup>10</sup> Therefore, in developing countries with relatively small commercial markets and low levels of disposable income, there is very little incentive for pharmaceutical companies to conduct extensive research and development in creating drugs for life-threatening diseases limited mostly to the developing world.<sup>11</sup> Only 1% of the 1,400 new medicines created in the last 25 years were developed for the treatment of tropical diseases (AIDS, malaria, tuberculosis, etc.), despite tropical diseases killing tens of thousands of people each year.<sup>12</sup> Tropical diseases are almost entirely confined to the developing world and again, do not represent a profitable market for the pharmaceutical industry.<sup>13</sup> The developed country argument that patent protection facilitates innovation and thereby improves overall world health is rebutted

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<sup>7</sup> In 2001, 39 pharmaceutical companies attempted to put pressure on the South African government by suing them based on South Africa's 1997 Medicines and Related Substances Control Act, Act. No. 90 of 1997. Hoen, *supra* note 1 at 1.

<sup>8</sup> Rajeev Dhavan, *The Patent Controversy*, The Hindu, Dec. 10, 2004, available at <http://www.hindu.com/2004/12/10/stories/2004121002361000.htm> (last visited Apr. 10, 2005).

<sup>9</sup> Hoen, *supra* note 1 at 2.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.* at 3.

<sup>12</sup> *Id.* at 2.

<sup>13</sup> *Id.* at 3.

with data showing that although patent protection has increased over the last 20 years, the drug innovation rate has fallen and the number of drugs with little or no therapeutic gain has increased.<sup>14</sup> “Essential medicines are not a luxury whose availability can be left to private market forces only, but an essential component of the fulfillment of the right to health.”<sup>15</sup>

It is important not to get lost in the legal issues and remember the human side of this problem.<sup>16</sup> “[E]ffective medicines that dramatically increase the life expectancy of people living with AIDS became available in Europe and North America a decade ago.”<sup>17</sup> However, despite the existence of these drugs, the World Health Organization (WHO) has found that nearly two billion people in developing countries still lack regular access to vital medicines.<sup>18</sup> Even with major progress in disease detection and treatment, eleven million people will die each year, most of them in developing countries, as a result of preventable and treatable infectious diseases.<sup>19</sup> Several millions more people in developing countries will suffer with prolonged battles of sickness and disability.<sup>20</sup> The premature death, sickness, and disability resulting from infectious diseases could be avoided if developing countries had better access to affordable medicines.<sup>21</sup>

In an increasingly interdependent world, where poverty, disease, violence, crime, war, regional conflicts and human rights and environmental [a]buses persist . . . clear international standards will help ensure that business will be part of the solution to today’s problems and not – knowingly or unknowingly – exacerbate them.<sup>22</sup>

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<sup>14</sup> *Id.* at 3.

<sup>15</sup> Hoen, *supra* note 1 at 6.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Cut the Cost - Patent Injustice: How World Trade Rules Threaten the Health of Poor People*, Oxfam Briefing Report, Feb. 2001, available at [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/downloads/patentinjustice.pdf](http://www.oxfam.org.uk/what_we_do/issues/health/downloads/patentinjustice.pdf) (last visited Apr. 10, 2005).

<sup>19</sup> *Id.* at 3.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at 3.

<sup>22</sup> Mauro Guarinieri, *U.N. Body Favors Scrutiny Of Corporations*, European AIDS Treatment Group (EATG), Aug. 19, 2004, available at <http://www.eatg.org/modules.php?op=modload&name=News&file=article&sid=14> (statement from the U.N. Wire, Aug. 13, 2004)(last visited Apr. 10, 2005).

It is crucial that international and domestic rules affecting research and development (R&D) and availability of medicines must be primarily motivated by global public health needs rather than simple industrial, economic, or commercial considerations.<sup>23</sup> With the dramatic increase in infectious diseases (AIDS, tuberculosis, and malaria) and the marginalization by pharmaceutical companies and governments of health problems not affecting the developed world, strong international support is needed to defend global public health.<sup>24</sup> All countries must recognize the importance of improving global health by combating neglected diseases.<sup>25</sup> Developed and developing country governments can combat neglected diseases by ensuring sufficient, sustainable, and long-term financing to address R&D needs and by working towards changing the way health R&D priorities are set and financed.<sup>26</sup> Although the global patent system has a significant role in stimulating investment and innovation, it also should balance the desire to reward inventors with the greater need to allow people to benefit from these inventions thereby emphasizing the importance of global public health.<sup>27</sup>

[I]n the pharmaceutical sector the winners will be the large northern-based transnational companies which, as a result of the lengthened patent protection provided by WTO rules, will be able to sell their new medicines at higher prices. The losers are likely to be the millions of people who will be unable to afford vital new medicines, and hard-pressed government health services. This situation will undermine efforts to increase productivity and eradicate poverty, and will result in a widening of the gap between rich and poor nations.<sup>28</sup>

This comment will analyze the need to amend and revise the current global pharmaceutical patent system under TRIPS to take into account the needs of developing countries and overall public health. This comment will emphasize that the current international trade rules, which although administered by the WTO, are dictated by developed country

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<sup>23</sup> Hoen, *supra* note 1 at 6.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at 7.

<sup>26</sup> *Id.*

<sup>27</sup> *Cut the Cost*, *supra* note 18 at 2.

<sup>28</sup> *Id.*

governments and powerful pharmaceutical companies, and therefore, without reform will further diminish the access of poor people in developing countries to vital medicines. Part II of this comment will provide a general overview of the international trade law governing patents on pharmaceuticals focusing specifically on the development of the current global pharmaceutical patent system, which was originally created by the WTO's Trade Related Aspects of Intellectual Property Law (TRIPS) in 1994, supplemented by the WTO's Doha Declaration and the WTO's Decision on Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health. Further, it will discuss the implicit and explicit exceptions to TRIPS provided within TRIPS Articles 8, 27, 30, 31, and 73. Part III will provide some general arguments used by developed countries to justify the imposition of stringent patent laws on developing countries and will argue against strong pharmaceutical patent protection in developing countries. Part IV will discuss the implications of TRIPS for developing countries, specifically their access to pharmaceuticals in an international trade environment. Further, it will show how the WTO is restricting competition, increasing prices, and limiting access to essential medicines. Part V will discuss the current patent laws of two crucial developing countries, India and South Africa. Part VI will provide possible solutions and considerations for reform of the global patent protection system under TRIPS. Part VII will conclude the comment with a brief summary.

## II. INTERNATIONAL TRADE LAW GOVERNING PATENTS ON PHARMACEUTICALS

### *A. The WTO's Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS).*

The Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), adopted by the World Trade Organization (WTO) at the end of the Uruguay Round in 1994, came into effect on January 1, 1995 as package deal included in the WTO/General Agreement on Tariffs

and Trade (GATT).<sup>29</sup> In order to become a member of the WTO, a country must agree to become subject to the broad WTO/GATT Agreement, which includes these TRIPS patent provisions.<sup>30</sup> Developed countries designed TRIPS based on their own intellectual property regimes and placed it within the 1995 WTO/GATT Agreement to create binding international patent obligations.<sup>31</sup> TRIPS created a common set of international intellectual property rules establishing minimum levels of patent protection that all countries within the WTO must give to other member countries.<sup>32</sup> Potential competitors are prohibited from producing and marketing cheap generics of these pharmaceutical products for a twenty-year period.<sup>33</sup> Thereby giving the pharmaceutical patent holder a monopoly based on the exclusive marketing rights on its patented product for at least those twenty years.<sup>34</sup>

The WTO's Dispute Settlement Board enforces TRIPS to ensure member country compliance.<sup>35</sup> All member country governments must comply with TRIPS by introducing these stringent patent laws domestically or face severe penalties from the WTO.<sup>36</sup> Although this may seem like an easy task, most developing countries do not have strong domestic patent laws, therefore TRIPS provides an extremely high standard of patent protection.<sup>37</sup> If a member country fails to meet its obligations under TRIPS, the burden of proof is on the defending

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<sup>29</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

<sup>30</sup> Barnes, *supra* note 5 at 917.

<sup>31</sup> *Id.*

<sup>32</sup> Bonita de Boer, *TRIPS, AIDS, and Generic Drugs*, AVERT.ORG, Jan. 19, 2005, available at <http://www.avert.org/generic.htm> (last visited Apr. 10, 2005).

<sup>33</sup> *Cut the Cost*, *supra* note 18 at 11.

<sup>34</sup> *Id.* at 5.

<sup>35</sup> *Id.* at 18.

<sup>36</sup> *Id.* at 18.

<sup>37</sup> Barnes, *supra* note 5 at 919-934.

country.<sup>38</sup> If the defending country fails to meet its burden, the WTO's Dispute Settlement Board most often allows the prosecuting country to impose trade sanctions.<sup>39</sup>

By restricting the right of governments to allow the production, marketing, and import of low-cost copies of patented medicines (called generic drugs), the WTO's rules will restrict competition, increase prices, and further reduce the already limited access of poor people to vital medicines.<sup>40</sup>

TRIPS was theoretically designed as a social policy tool to encourage innovation by establishing minimum standards for the protection of intellectual property including patents on pharmaceuticals; however, these standards were developed based on Western European and North American property law by wealthy countries with little regard for the needs of developing countries.<sup>41</sup> The major selling point for the issuance of patents is in theory by "providing limited exclusivity to the 'inventors' of products . . . innovation will be promoted and society as a whole will benefit from the availability of new and improved products."<sup>42</sup> In reality, the twenty-year global patent protection system has created an extremely profitable and powerful group of multinational pharmaceutical companies that by law are allowed to deny access to life-saving medicines.<sup>43</sup>

#### 1. TRIPS Generally: Preamble & Article 7 (Objectives)

The express intent of TRIPS, declared in the preamble is "to ensure that measures and procedures to enforce intellectual property rights [including patents] do not themselves become barriers to legitimate trade."<sup>44</sup> TRIPS Article 7 provides that the protection of intellectual property rights will promote both technological innovation and the transfer and dissemination of

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<sup>38</sup> *Cut the Cost*, *supra* note 18 at 18.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* at 3.

<sup>41</sup> Hoen, *supra* note 1 at 1-2.

<sup>42</sup> *Id.* at 2.

<sup>43</sup> *Id.*

<sup>44</sup> TRIPS Agreement, *supra* note 29, preamble.

technology “to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare.”<sup>45</sup>

## 2. TRIPS Limited Implicit and Explicit Exceptions (“Public Health Safeguards”)

Although overall TRIPS grants strong patent protection to member countries, there are implicit and explicit exceptions contained in TRIPS Article 8, 27, 30, 31, and 73 that if used effectively could provide developing countries with ammunition to combat some of their lack of access problems.<sup>46</sup>

### a. Implicit Exceptions: TRIPS Article 8 (Principles) & TRIPS Article 27 (Patentable Subject Matter)

TRIPS Article 8 provides a guiding principle upon which all other provisions of TRIPS should be read.<sup>47</sup> Article 8 mandates that in creating domestic laws, member countries “may, in formulating and amending their national laws and regulations, adopt measures necessary to protect *public health* and nutrition, and to promote the *public interest* in sectors of vital importance to their *socio-economic* and *technological* development.”<sup>48</sup> Therefore, Article 8 provides possible grounds that developing country governments could use to combat tropical diseases such as HIV-AIDS.<sup>49</sup>

First, it allows governments to adopt measures for the protection of public health.<sup>50</sup> Second, it allows governments to adopt measures for the protection of its own country’s socio-economic and technological development, which may provide possible grounds for developing country governments to combat the effect of the HIV-AIDS crisis on labor, industrial, farming,

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<sup>45</sup> TRIPS Agreement, *supra* note 29, art. 7.

<sup>46</sup> Wesley A. Cann, Jr., *On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries For Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism*, 25 U. PA. J. INT’L ECON. L. 755, 808-826 (2004).

<sup>47</sup> *Id.* at 808.

<sup>48</sup> TRIPS Agreement, *supra* note 29, art. 8; Cann, *supra* note 46 at 808.

<sup>49</sup> Cann, *supra* note 46 at 808.

<sup>50</sup> *Id.*



and food markets.<sup>51</sup> Third, the use of the word “necessary” indicates that the government does not have complete discretion to use these measures, but that its use is subject to review by the WTO.<sup>52</sup> Although this seems restrictive, the WTO could use this discretion to instead help developing country governments combat life-threatening diseases.<sup>53</sup> For example, the WTO could grant a developing country government “substantial latitude . . . in the midst of a health crisis” pursuant to the clarification of TRIPS through the Doha Declaration and Decision discussed below.<sup>54</sup> Fourth, Article 8 is limited to such measures “consistent with the provisions” of TRIPS.<sup>55</sup> Again, this could be seen a limitation.<sup>56</sup> However, since Article 8 was intended to be a guiding principle, developing country governments can take public health and development measures reflected in the “flexibilities” contained in Articles 27, 30, 31, and 73, and still remain consistent with TRIPS pursuant to Article 8.<sup>57</sup> Finally, Article 8 allows developing country governments “to prevent the ‘abuse’ of intellectual property rights or to prevent practices that ‘unreasonably restrain trade or adversely affect the international transfer of technology.’”<sup>58</sup> These terms “abuse,” “unreasonably restrain trade,” and “adversely affect” are subjective and are open to different cultural and economic interpretations, which could provide developing country governments will additionally ways to improve access to pharmaceuticals.<sup>59</sup>

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<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> TRIPS Agreement, *supra* note 29, art. 8 (emphasis added).

<sup>56</sup> Cann, *supra* note 46 at 809.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> “The developing countries, for example, have indicated that an “abuse” of intellectual property rights could include the charging of excessively high prices for patented pharmaceuticals, the selling of pharmaceuticals at prices beyond “reasonable” profit margins, or the failure to offer products in quantities sufficient to meet market demand.” TRIPS Agreement, *supra* note 29, art. 8; Cann, *supra* note 46 at 809.

Other possible grounds, which developing country governments might be able to combat infectious diseases such as HIV-AIDS are found in Articles 27.<sup>60</sup> TRIPS Article 27 provides that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.”<sup>61</sup> There is considerable room for flexibility and interpretation of TRIPS Article 27.<sup>62</sup> Developing country governments can create domestic patent systems benefiting their own countries by developing their own standards and interpretations of the undefined terms in TRIPS Article 27 in their own domestic jurisprudence.<sup>63</sup> For example, Article 27 (2) allows countries to “exclude from patentability inventions . . . necessary to protect ordre public or morality, including to protect human, animal or plant life or health.”<sup>64</sup> Developing country governments could argue that the HIV-AIDS crisis is a moral or public issue, thereby incorporating social, ethical, and moral considerations into the domestic patent regime.<sup>65</sup> However, this flexibility does not provide developing countries with a clear answer on how to provide better access to lifesaving drugs because the denial of patentability of a lifesaving drug would be accompanied by denial of any commercial exploitation of the drug within that country including the domestic manufacture of generic versions or compulsory licensing of the drug for a profit.<sup>66</sup> Arguably, developing country governments could, after denying patentability, produce and distribute the product non-commercially either through a state-owned enterprise or private non-profit manufacturer.<sup>67</sup>

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<sup>60</sup> Cann, *supra* note 46 at 810.

<sup>61</sup> TRIPS Agreement, *supra* note 29, art. 27.

<sup>62</sup> Cann, *supra* note 46 at 810.

<sup>63</sup> *Id.*

<sup>64</sup> TRIPS Agreement, *supra* note 29, art. 27 para. 2.

<sup>65</sup> Cann, *supra* note 46 at 811.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.* at 812.

[I]f a nation takes the position that the prevention and treatment of the HIV/AIDS epidemic is necessary to protect the ordre public, . . . [TRIPS] . . . would apparently allow that nation to deny patent protection to relevant pharmaceuticals and then distribute those products, assuming they are attainable, on a non-profit, non-commercial basis. Since there could be no discrimination between the rights of foreign and domestic producers, as neither would be allowed to engage in commercial exploitation, such a strategy would appear consistent with the terms of . . . [TRIPS].<sup>68</sup>

b. Explicit Exceptions: TRIPS Article 30 (Exceptions to Rights Conferred) & TRIPS Article 31 (Other Use Without Authorization of the Right Holder) & Article 73 (Security Exceptions)

In addition to the flexibility inherent in the subjective language of Articles 8 and 27, there are explicit exceptions under TRIPS Articles 30, 31, and 73, which developing country governments should utilize to improve access to essential pharmaceuticals.<sup>69</sup> “Any exceptions to the exclusive rights conferred by a patent or other use of the subject matter of a patent without the authorization of the patent holder must be in accordance with either TRIPS Article 30 or TRIPS Article 31.”<sup>70</sup> Through these limited exceptions, developing country governments have a few significant tools that allow them to balance the public interest of their citizens with the proprietary claims of patent holders.<sup>71</sup>

First, the developing country government can override a patent by authorizing a compulsory license for production of a drug under TRIPS Article 31.<sup>72</sup> TRIPS Article 31 allows WTO member countries to authorize “other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government.”<sup>73</sup> A compulsory patent license is “when a government allows a third party to make, use or sell a patented product or a product obtained through a patented process without the

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<sup>68</sup> *Id.*

<sup>69</sup> *Id.* at 813.

<sup>70</sup> “TRIPS Article 30 is concerned with limited exceptions to the rights conferred by a patent other than use by the government or third parties authorized by the government, and therefore, is not affected by or mentioned in either the Doha Declaration or the Decision.” Therefore, no further discussion of Article 30 is needed. Markus Nollf, *Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health and the Decision of the WTO Regarding its Implementation: An “Expeditious Solution”?*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 291 (2004).

<sup>71</sup> *Cut the Cost*, *supra* note 18 at 19.

<sup>72</sup> *Id.*

<sup>73</sup> Nollf, *supra* note 70 at 296.

consent of the patent owner.”<sup>74</sup> The “use” referred to in the preamble to TRIPS Article 31 (“use by . . . third parties authorized by the government”) includes granting compulsory licenses.<sup>75</sup> For compulsory licenses, TRIPS Article 31 mandates that:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. . . . ;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized . . . .
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;<sup>76</sup>

Therefore, Article 31 allows governments to issue compulsory licenses on public health grounds to authorize production of patented drugs without the consent of patent holders, subject to adequate compensation.<sup>77</sup> Governments can also issue compulsory licenses in response to national health emergencies.<sup>78</sup> “In the case of ‘a national emergency or other circumstances of extreme urgency’ or ‘a public health crisis,’ . . . subparagraph (b) [of TRIPS Article 31] merely requires that ‘the right holder shall, nevertheless, be notified as soon as reasonably

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<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> TRIPS Agreement, *supra* note 29, art. 31 fn.7; Nollf, *supra* note 70 at 296.

<sup>77</sup> *Cut the Cost*, *supra* note 18 at 5.

<sup>78</sup> *Id.* at 19.

practicable.”<sup>79</sup> Finally, developing country governments can also issue compulsory licenses to curtail excessive prices.<sup>80</sup>

Governments can grant compulsory licenses for domestic production or importation of pharmaceuticals.<sup>81</sup> However, there are significant obstacles for developing countries in being able to grant compulsory licenses either for domestic production or for parallel importation.<sup>82</sup> In order for a government to make effective use of a compulsory license for domestic production under TRIPS Article 31, it must have a reasonably sophisticated pharmaceutical industry to produce medicine and it must have a manufacturer with sufficient manufacturing capacity to create economies of scale to keep the costs down and the price of the medicine affordable.<sup>83</sup> Further, to utilize a compulsory license for importation under TRIPS Article 31, the government must be able to import the pharmaceuticals at an affordable price in the quantity and quality required.<sup>84</sup> Many governments cannot utilize the compulsory license for domestic production because they do not have sufficient manufacturing capacity.<sup>85</sup>

Also many governments cannot utilize the compulsory license for importation because a potential importer is prohibited from manufacturing and exporting the drug from a member country with sufficient manufacturing capacity.<sup>86</sup> Although a compulsory license might be granted for the domestic manufacture of a drug in a member country with sufficient manufacturing capacity, this potential importing member country is prohibited from exporting a large fraction of the drugs made under that compulsory license.<sup>87</sup> This is because TRIPS Article

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<sup>79</sup> TRIPS Agreement, *supra* note 29, art. 31 fn. 7 (b); Nollf, *supra* note 70 at 298.

<sup>80</sup> *Cut the Cost*, *supra* note 18 at 19.

<sup>81</sup> Nollf, *supra* note 70 at 298.

<sup>82</sup> *Id.*

<sup>83</sup> Nollf, *supra* note 70 at 298; *Cut the Cost*, *supra* note 18 at 19.

<sup>84</sup> Nollf, *supra* note 70 at 298; *Cut the Cost*, *supra* note 18 at 19.

<sup>85</sup> Nollf, *supra* note 70 at 298.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

31(f) permits issuance of compulsory licenses only if it is “predominantly for the supply of the domestic market of the Member authorizing such use.”<sup>88</sup> Therefore, pursuant to these strict compulsory license requirements, developing countries and least developed countries (LDCs) cannot obtain drugs through importation at an affordable price in the quantity and quality required.<sup>89</sup> As discussed below, this restriction on the use of compulsory licenses for importation is even more significant as many developing member countries (like India), who until recently have been able to export huge quantities of generic drugs because its domestic patent laws were not TRIPS compliant, were required to enact TRIPS compliant domestic laws on January 1, 2005.<sup>90</sup> Therefore, the developing countries with sufficient manufacturing capacity will now be more limited in their ability to export medicines to other developing and LDCs, which do not have sufficient manufacturing capacity to produce life-saving medicines.<sup>91</sup>

Second, a government can engage in parallel importing.<sup>92</sup> Governments can allow the importation of a patented product, which is marketed elsewhere at prices lower than those in its domestic market.<sup>93</sup> This means importing a patented drug from wherever it is sold the cheapest, regardless of the wishes of the patent holder.<sup>94</sup> Although parallel importing is not specifically mentioned by TRIPS, pharmaceutical companies and developed country government (U.S.) are motivated to make sure that it is banned through domestic patent legislation.<sup>95</sup>

The last exception is under TRIPS Article 73.<sup>96</sup> Article 73 declares that nothing in TRIPS shall prohibit a member country from taking any action “which it considers necessary for

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<sup>88</sup> TRIPS Agreement, *supra* note 29, art. 31, fn.7 (f); Nollf, *supra* note 70 at 298.

<sup>89</sup> Nollf, *supra* note 70 at 298.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Cut the Cost*, *supra* note 18 at 5.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* at 19.

<sup>95</sup> *Id.* at 19.

<sup>96</sup> TRIPS Agreement, *supra* note 29, art. 73.

the protection of its essential security interests . . . taken in time of war or other emergency in international relations.”<sup>97</sup> Additionally, TRIPS Article 73 declares that no member country shall be prohibited “from taking any action in pursuance of its obligation under the United Nations Charter for the maintenance of international peace and security.”<sup>98</sup> This security exception, if exercised, can relieve a member country from virtually all of its substantive obligations under TRIPS.<sup>99</sup>

*B. The WTO’s Doha Declaration- Access to Medicine for All*

Whether exceptions to patent protection can be made in the case of a public health crisis, was one of the critical issues dominating the discussion at the WTO’s Fourth Ministerial Conference in Doha, Qatar in November of 2001.<sup>100</sup> During this Conference, the WTO released its Declaration on the TRIPS Agreement and Public Health (Doha Declaration).<sup>101</sup> The WTO recognized some of the lack of access concerns raised by developing countries when it adopted the Doha Declaration.<sup>102</sup> In order to attempt to increase access to pharmaceuticals, the Doha Declaration granted countries the power to manufacture generic drugs made before the introduction of TRIPS and the power to produce newer drugs through compulsory licensing.<sup>103</sup> The 2001 Doha Declaration indicated that the WTO and TRIPS “can and should be interpreted

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<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> Cann, *supra* note 46 at 822.

<sup>100</sup> Nolff, *supra* note 70 at 292.

<sup>101</sup> *Id.* at 292.

<sup>102</sup> Hoen, *supra* note 1 at 4.

<sup>103</sup> “A compulsory license is a government license that enables people other than the patent holder to copy patented or copyrighted products and processes. Governments can issue them if a patent owner abuses their rights by, for example, failing to offer their produce on the market, or offering it at a price that is too high for potential buyers to afford. Competitors can then produce the produce or use the process under government license without fear of prosecution. In the case of generic drugs, compulsory licenses can be issued because of the high (and for developing nations, often unaffordable) prices charged by the major pharmaceutical companies for their products.” Boer, *supra* note 32 at 2.

and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicine for all."<sup>104</sup>

Therefore, the Doha Declaration more clearly outlined the flexibilities contained in TRIPS that countries could use to overcome the barriers created by patents.<sup>105</sup> Further, the Doha Declaration extended the transitional period until 2016, during which the LDCs are not obliged to enforce or grant patents on pharmaceutical products.<sup>106</sup> Unfortunately, the WTO's Doha Declaration failed to resolve whether further exceptions could be made to supply pharmaceuticals to countries, which lack sufficient manufacturing capacity to make effective use of TRIPS' compulsory licensing provisions.<sup>107</sup> With regard to this unsettled issue, paragraph 6 of the Doha Declaration simply declared, "We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."<sup>108</sup>

*C. The WTO's Decision "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health"*

Other efforts to solve this lack of access issue were attempted in November 2002 and February 2003.<sup>109</sup> Finding an acceptable "expeditious solution" became a priority to be solved before the WTO's Fifth Ministerial Conference in Cancun, Mexico.<sup>110</sup> In August 2003, the WTO General Council adopted a Decision entitled "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (Decision).<sup>111</sup> In response to

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<sup>104</sup> World Trade Organization (WTO) – Doha Ministerial Conference 2001: Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, 41 I.L.M. 755 (2001) [hereinafter Doha Declaration] para. 4; Dhavan, *supra* note 8.

<sup>105</sup> Hoen, *supra* note 1 at 4.

<sup>106</sup> Hoen, *supra* note 1 at 4.

<sup>107</sup> Nolff, *supra* note 70 at 293.

<sup>108</sup> Doha Declaration, *supra* note 104, para. 6.

<sup>109</sup> Nolff, *supra* note 70 at 293.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*



Paragraph 6 of the Doha Declaration, immediately before the Cancun Ministerial Conference, the WTO General Council approved this Decision, which was designed to make it easier for poor developing countries that lack domestic capacity to import cheaper generic drugs produced under compulsory licenses.<sup>112</sup> Normally, under TRIPS, it would be illegal to copy a brand name drug that was still under a patent.<sup>113</sup> However, as discussed above, it was agreed in the Doha Declaration that TRIPS should not prevent member countries from taking measures to protect the public health of its citizens.<sup>114</sup> Therefore, this Decision was intended to supplement the Doha Declaration by providing clarification of the steps necessary to improve access to essential medicines.<sup>115</sup> Formally, the Decision is considered an interim good faith waiver of TRIPS Article 31(f) to protect public health and is applicable until TRIPS is amended.<sup>116</sup> The Decision allows any member country that produces generic copies of patented pharmaceuticals under a compulsory license to export these products to eligible importing countries (i.e., countries without sufficient manufacturing capacity).<sup>117</sup>

In order to improve access to essential medicines, a member country lacking sufficient manufacturing capacity must follow the general step-by-step process laid out by the WTO in the Decision.<sup>118</sup> First, an importing member country must notify the TRIPS Council of its request to import certain pharmaceuticals indicating the names and expected quantities to be imported.<sup>119</sup> Second, the importing member country must prove it has insufficient pharmaceutical

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<sup>112</sup> Cann, *supra* note 46 at 817.

<sup>113</sup> Boer, *supra* note 32 at 2.

<sup>114</sup> *Id.*

<sup>115</sup> Cann, *supra* note 46 at 817-818.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> World Trade Organization (WTO) General Council: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Sept. 1, 2003, 43 I.L.M. 509 (2004) [hereinafter The Decision], para. 2(a); Cann, *supra* note 46 at 818.

manufacturing capacity for the requested pharmaceuticals.<sup>120</sup> Third, the exporting member country must issue a compulsory license reflecting that only the quantity necessary to meet the specified needs of the importing member country will be manufactured.<sup>121</sup> Fourth, the compulsory license must indicate that the entire quantity produced for the purpose of this license will be exported to the specified importing member country.<sup>122</sup> Fifth, “adequate remuneration” or compensation should be paid to the patent holder by the exporting member country taking into account the “economic value to the importing Member of the use that has been authorized.”<sup>123</sup> Finally, the Decision requires all member countries to take “reasonable measures” to prevent the re-exportation of the generic drugs produced under these compulsory licenses and to provide “effective legal means for the prevention of diversion.”<sup>124</sup>

Although this Decision was intended to provide clarification, instead it created a complex mechanism that has not improved drug access in developing countries and has not aided generic drug production in countries like India.<sup>125</sup> The Decision needlessly complicated the exportation process by creating a mechanism that evaluates each situation on a country-by-country and drug-by-drug basis.<sup>126</sup> The WTO’s focus in the Decision on the smaller picture ignores the developing country manufacturers’ need to create economies of scale to continue to operate and provide the drugs at a reasonable price to developing countries that lack sufficient manufacturing capacity.<sup>127</sup>

The WTO appears to be attempting to improve developing countries lack of access concerns with the implicit and explicit exceptions contained within TRIPS, the Doha Declaration, and the Decision. All of these attempts to provide clarifications have needlessly

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<sup>120</sup> The Decision, *supra* note 119; Cann, *supra* note 46 at 818.

<sup>121</sup> The Decision, *supra* note 119; Cann, *supra* note 46 at 818.

<sup>122</sup> The Decision, *supra* note 119; Cann, *supra* note 46 at 818.

<sup>123</sup> The Decision, *supra* note 119 at para. 3; Cann, *supra* note 46 at 817.

<sup>124</sup> The Decision, *supra* note 119 at para. 4; Cann, *supra* note 46 at 817.

<sup>125</sup> Hoen, *supra* note 1 at 4-5.

<sup>126</sup> *Id.* at 5.

<sup>127</sup> *Id.*

added to the complication and confusion revolving around international pharmaceutical patent laws. Although, the WTO is attempting to improve access to pharmaceuticals for certain select countries suffering from a national emergency or a public health crisis, developing countries should not be held to the same level of stringent patent protection as developed western countries.

### III. PHARMACEUTICAL PATENT LAW IN DEVELOPING COUNTRIES

The protection of pharmaceuticals by patents involve complex issues, therefore there are strong arguments in favor and against providing patents in developing countries. In developed countries, intellectual property rights have in some respects evolved into a natural right.<sup>128</sup> Patent rights are now viewed almost as a fundamental entitlement in developed countries and this right attaches “to man as a human being much like equal protection, equality, and self-determination.”<sup>129</sup> “[A] fundamental right of man cannot be limited by territorial boundaries, and all nations (irrespective of wealth, history, culture, or need) must award universal acceptance.”<sup>130</sup> The current international patent system is argued to represent a balancing of interests designed to maximize global social welfare.<sup>131</sup>

A patentee receives exclusive rights over his or her creation for a limited period of time in exchange for a complete, public disclosure of the knowledge upon which the invention is based. Not only may the public use this knowledge upon the patent's term expiration, but also the knowledge may serve (even during the patent term itself) as the foundation for further advancement of science and technology in a variety of fields. In addition to this general dissemination, the monopoly that is granted serves to encourage the patentee to license the discovery so that the invention can be commercialized, technology can be transferred, and other products can be developed for the benefit of society. By ensuring protection for creative efforts, the patent system also provides the necessary incentive for inventiveness since creators will be able to profit from their R&D investments.<sup>132</sup>

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<sup>128</sup> Cann, *supra* note 46 at 782.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* at 783.

<sup>132</sup> *Id.* at 790.

*A. Developed Countries' Arguments for Stringent Patent Protection in Developing Countries*

The first argument used by developed countries to emphasize the importance of the international recognition of patents within an international trade environment is that patent protection encourages participation in the pharmaceutical industry by providing financial incentives.<sup>133</sup> “Patents create more certainty of potential profits at the end of the research cycle and decrease the risk of investment.”<sup>134</sup> Along those same profit-based lines, developed countries argue that stringent international patent protection is crucial in allowing pharmaceutical companies to recoup their substantial research and development (R&D) costs.<sup>135</sup> The pharmaceutical industry, unlike other industries, devotes the majority of its resources to R&D.<sup>136</sup> During the last twenty years, the U.S. pharmaceutical industry’s percentage of sales allocated to R&D increased from 11.9 percent in 1980 to 18.5 percent in 2001.<sup>137</sup> Therefore, developed countries argue the most effective way to continue to provide financial incentives for pharmaceutical companies is to their protect profit margins from being eroded by cheap generic drugs through internationally enforceable patent rights.<sup>138</sup>

Related to the first argument, the second major argument offered by developed countries to justify stringent international patent protection is strong patent protection fuels innovation.<sup>139</sup> Developed countries argue that by providing patents pharmaceutical companies will research and develop more drugs that will improve the overall global public health.<sup>140</sup> However, most of the developed countries’ arguments justifying stringent patent protection do not explicitly revolve

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<sup>133</sup> Sahar Asiz, *Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt’s Pharmaceutical Industry*, 10 ILSA J. INT’L & COMP. L. 1, 5 (2003).

<sup>134</sup> *Id.* at 4.

<sup>135</sup> *Id.* at 5.

<sup>136</sup> Barnes, *supra* note 4 at 914.

<sup>137</sup> *Id.*

<sup>138</sup> Asiz, *supra* note 133 at 4.

<sup>139</sup> *Id.* at 5-6.

<sup>140</sup> *Id.* at 5.

around their pharmaceutical companies' economic interests for obvious political reasons, but rather tend to emphasize the global benefits of stringent patent protection in general.<sup>141</sup> By providing pharmaceutical companies with a monopoly over the sale and distribution of their drugs for a fixed time period, developed countries argue that patents are supposed to create incentives for R&D activities in every country's private sectors.<sup>142</sup> This basically means that developing countries' ensuing concerns with high pharmaceutical prices and inaccessibility to essential medicines are countered with the developed country theory that too much access caused by weak patent protection will create more inaccessibility in the long run, resulting in the stagnancy of new drug discoveries.<sup>143</sup>

Third, developed countries argue that stringent patent protection is necessary to create an international trade environment.<sup>144</sup> Supporters of TRIPS argue that international law creating enforceable intellectual property rights are necessary to create an international economy and are a natural progression from the post-World War II economy.<sup>145</sup> Therefore, the inclusion of TRIPS as a WTO agreement is a requisite gradual move towards economic globalization.<sup>146</sup> “[T]he push for more secure and stable international trading systems, and the emergence of the hyper-connected international economy, have necessitated strict intellectual property protections.”<sup>147</sup>

The fourth argument offered by developed countries for the importance of international patent law emphasizes the benefits available to developing countries through technology transfer

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<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> Barnes, *supra* note 4 at 917.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> Matthew Kramer, Comment, *The Bolar Amendment Abroad: Preserving the Integrity of American Patents Overseas After the South African Medicines Act*, 18 DICK. J. INT'L L. 553, 557 (2000).

and foreign direct investment.<sup>148</sup> “TRIPS . . . encourages technology sharing, which could lead to pharmaceutical companies (both generic and multi-national) sharing expertise, giving more developing countries the capability to produce drugs for their own people.”<sup>149</sup> Developed countries argue that the benefits from strong patent protection will not be limited to their own rich and powerful pharmaceutical companies, but will assist local manufacturers in developing countries to establish their own R&D activities, which will be better suited to local needs.<sup>150</sup> In the international patent process, developing countries are supposed to benefit from the dissemination of knowledge required through patent disclosures, which can be used as inputs for more innovation.<sup>151</sup>

Therefore, IPRs [including patents] will support innovative behavior that adapts existing technologies to local needs of which the cumulative effect can ignite growth in knowledge and economic activity. The local firms will also have an equal opportunity to sell their products abroad in order to reap the higher profits currently enjoyed by western [multinational pharmaceutical enterprises] that own the majority of existing pharmaceutical patents.<sup>152</sup>

Developed countries argue stringent patent protection facilitates contracting between firms and increases technology transfer, thereby increasing the production of drugs and the efficiency of the R&D process for new drugs.<sup>153</sup> For example, technology transfer can occur through the shipment of advanced inputs to subsidiaries in local markets in developing countries.<sup>154</sup> In this way, pharmaceutical companies can theoretically indirectly share blueprints, product designs, and skilled producer services.<sup>155</sup>

Along these lines, developed countries argue that developing countries will benefit from international pharmaceutical patent law through foreign direct investment

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<sup>148</sup> Asiz, *supra* note 133 at 6.

<sup>149</sup> Boer, *supra* note 32.

<sup>150</sup> Asiz, *supra* note 133 at 6.

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 7.

<sup>155</sup> *Id.*

from wealthy member countries to poor member countries with stable patent protection systems.<sup>156</sup> With strong international patent protection, pharmaceutical companies should be more willing to commit to “foreign direct investment, joint ventures, and licensing agreements in developing countries.”<sup>157</sup> Developed countries argue that as patent laws are strengthened in developing countries, foreign direct investment is likely to increase “in complex, but easily copied technologies” including pharmaceuticals.<sup>158</sup> Without stringent patent protection not only will the providers of foreign direct investment hesitate to invest in these developing countries, but many pharmaceutical companies may refuse to export their drugs in order to protect their global profit margins.<sup>159</sup> Therefore, the thrust of the developed countries’ argument is it is the developing world’s responsibility to provide a business environment friendly to the needs of wealthy, multinational pharmaceutical companies in order to have access to essential medicines.<sup>160</sup>

*B. Developing Countries’ Arguments Against Stringent Patent Protection in Developing Countries*

Developing countries argue that instead of patents being viewed as a fundamental or natural right, patent protection should instead merely represent a conscious governmental decision to maximize social welfare and patents should instead be viewed as governmental “grants,” “licenses,” or “privileges,” which could then be conditioned or even refused rather than universally accepted.<sup>161</sup> Unfortunately for developing countries whether rightfully or wrongfully, these intellectual “property” rights have been placed on a “moral plane” by powerful

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<sup>156</sup> Asiz, *supra* note 133 at 6.

<sup>157</sup> *Id.* at 7.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> Cann, *supra* note 46 at 783.

developed countries and have been removed from political and ideological challenge.<sup>162</sup>

Although, developed countries have strong arguments in favor of stringent patent protection, developing countries have even strong counter-arguments that patent protection should be more flexible in developing countries.

First, in response to developed countries' arguments that stringent international patent protection is needed to allow pharmaceutical companies to continue to operate, to create financial incentive for innovation, and to allow them to recoup their R&D costs, developing countries argue that it is unfair to deny access to essential medicines simply because poor developing countries do not have sufficient manufacturing capacity to produce or develop these essential medicines. In fact, "[o]nly a few developed countries (Belgium, France, Germany, Italy, Japan, Netherlands, Sweden, Switzerland, UK, and United States) in the world have the sufficiently sophisticated pharmaceutical industry and significant research base necessary to conduct complex research and development activities."<sup>163</sup> Further, many monopolist drug companies receive tax benefits and foundation funds that help them finance their R&D costs.<sup>164</sup> However, developed countries have used this power to restrict access to developing countries and to place significant pressure on developing countries to strictly conform their domestic patent laws to TRIPS.<sup>165</sup>

Second, although developed countries argue that "[u]ltimately, the economic incentives derived from monopoly power of individual pharmaceuticals will benefit overall global welfare through the discovery of new drugs and therapies that cure debilitating, if not fatal, diseases."<sup>166</sup> In reality, only a few pharmaceutical companies (including GlaxoSmithKline and Novartis) have

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<sup>162</sup> *Id.* at 782-783.

<sup>163</sup> Asiz, *supra* note 133 at 4.

<sup>164</sup> Dhavan, *supra* note 8.

<sup>165</sup> Asiz, *supra* note 133 at 4.

<sup>166</sup> *Id.* at 5.



increased their investment in infectious-disease research and even fewer (only GlaxoSmithKline) have increased their investment in vaccine development, but only on a small scale.<sup>167</sup> Developed countries argue that one of the disadvantages arising out of weak patent protection in developing countries is corresponding a lack of focus by pharmaceutical companies on diseases and illnesses prevalent in developing countries.<sup>168</sup> However, it is clear that without great financial incentives pharmaceutical companies will not focus on diseases and illnesses prevalent in developing countries.

Third, the developed country theory that stronger patent protection is essential to promote a stable international economy<sup>169</sup> has created a small group of powerful pharmaceutical multinational enterprises (MNEs) worldwide with significant influence in shaping domestic and international patent policies.<sup>170</sup> Unfortunately, it is primarily these pharmaceutical companies' business concerns that dictate developed countries' approaches to implementing patent rights on an international scale.<sup>171</sup> In reality, these patent rights give pharmaceutical companies monopolies over lifesaving medicines and allow the pharmaceutical company to restrict competition, limit access, and increase prices.

Finally, contrary to the developed country argument that patent protection facilitates technology transfer and foreign direct investment, developing countries argue that the current system does not transfer technology or increase foreign direct investment. Developing countries argue contrary to the argument that the creation of stringent international patent protection will

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<sup>167</sup> Michael Bailey, *Big Pharma's Tiny Gestures*, European AIDS Treatment Group (EATG), May 19, 2004, available at <http://www.eatg.org/modules.php?op=modload&name=News&file=article&sid=244> (last visited Apr. 10, 2005).

<sup>168</sup> "For example, currently 99% of the global disease burden is concentrated in the low and middle-income countries, but only 4.3% of global health-related R&D expenditures address those diseases." Asiz, *supra* note 133 at 5.

<sup>169</sup> Barnes, *supra* note 4 at 918.

<sup>170</sup> Asiz, *supra* note 133 at 4.

<sup>171</sup> *Id.*

provide developing countries with more access to up-to-date technologies through technology transfer, instead developing countries become isolated from new technologies and the only solution is for them to begin building their own technological knowledge from scratch.<sup>172</sup> This is a nearly impossible mission given their economic constraints.<sup>173</sup>

TRIPS should not have been included within the WTO/GATT Agreement.<sup>174</sup>

Monopolies should have no place in an international free trade agreement.<sup>175</sup> Unfortunately, so far developed country governments have been more spirited in defending its pharmaceutical companies than developing countries (like India and South Africa) have been able to defend its poor who desperately need access to life sustaining drugs.<sup>176</sup>

#### IV. IMPLICATIONS FOR DEVELOPING COUNTRIES: ACCESS TO PHARMACEUTICALS IN AN INTERNATIONAL TRADE ENVIRONMENT- HOW THE WTO IS RESTRICTING COMPETITION, INCREASING PRICES, AND LIMITING ACCESS

##### *A. Creating Corporate Pharmaceutical Monopolies Through the Auspices of Free Trade*

##### *1. Big Money Means Big Political Power for the Pharmaceutical Industry*

Although created under the auspices of free trade, TRIPS, was the product of intense lobbying by the world's largest and most powerful pharmaceutical companies (Merck, Pfizer, GlaxoSmithKline, and Eli Lilly) and of intense political pressure by the world's largest and most powerful countries (U.S., Europe, and Japan).<sup>177</sup> To put it in perspective, the financial power of these pharmaceutical companies relative to developing countries is reflected by their market capitalization, which is collectively greater than the economies of Mexico and India and twice the gross national product of sub-Saharan Africa.<sup>178</sup> This financial power has been converted

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<sup>172</sup> *Id.* at 6.

<sup>173</sup> *Id.*

<sup>174</sup> Dhavan, *supra* note 8.

<sup>175</sup> *Id.*

<sup>176</sup> *Id.*

<sup>177</sup> *Cut the Cost*, *supra* note 18 at 11.

<sup>178</sup> *Id.*

into tremendous political influence both nationally and internationally.<sup>179</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA), the most powerful pharmaceutical industry lobby in the U.S., was a driving force in getting TRIPS adopted and now plays a leading role in encouraging the Bush Administration to use bilateral negotiations and unilateral economic sanctions<sup>180</sup> against countries that PhRMA believes offer inadequate patent protection.<sup>181</sup> Granting patent protection to pharmaceutical companies creates pharmaceutical monopolies, which in turn translates into higher drug prices based on the companies' ability to limit access to these drugs.<sup>182</sup> To reduce drug prices, the WTO should consider a major reformation of TRIPS, in order to create a competitive market for generic drugs in developing countries.<sup>183</sup>

## 2. With Big Power Comes Big Responsibility: Pharmaceutical Companies' Duty to Supply- Patents and Prices

Pharmaceutical companies should accept that their long-term economic interest is better served by accepting corporate social responsibility including adopting a more flexible approach to drug prices and patents in developing countries.<sup>184</sup> "Patents are not a gift for drug companies to exercise power without responsibility."<sup>185</sup> These pharmaceutical companies, by showing a greater sensitivity to the urgent health needs of developing countries, can restore the legitimacy of the pharmaceutical industry, as its power ultimately depends on the trust of the public and governments.<sup>186</sup>

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<sup>179</sup> *Id.*

<sup>180</sup> Including suggesting who should be on the U.S. Trade Representative's Section 301 Priority Watch List.

<sup>181</sup> *Preventing the Cure: Corporate Lobbying and Fair Access to Medicines*, Oxfam Briefing Paper on Pfizer Based on Pfizer's Meeting with Oxfam in N.Y.C., June 4, 2001 [hereinafter *Pfizer*], available at [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/downloads/cb\\_pfizer.pdf](http://www.oxfam.org.uk/what_we_do/issues/health/downloads/cb_pfizer.pdf) (last visited Apr. 10, 2005).

<sup>182</sup> Hoen, *supra* note 1 at 1.

<sup>183</sup> Bailey, *supra* note 167.

<sup>184</sup> *Id.*

<sup>185</sup> Dhavan, *supra* note 8 at 3.

<sup>186</sup> Bailey, *supra* note 167.

In January 2004, after the Brazilian government threatened to override patents and license generic manufacture, five international pharmaceutical companies cut the price of their drugs allowing the Brazilian government to save approximately 80 million dollars<sup>187</sup> in its annual drug bill for anti-retrovirals (ARVs).<sup>188</sup> This tremendous savings will help to ensure the sustainability of Brazil's world-renowned treatment program.<sup>189</sup> In addition, Bristol-Myers Squibb surrendered its exclusive right to Thailand to produce its ARV (didanosine or ddI) after a three-year legal battle initiated by local activists, who claimed that the high price of the ARV was an infringement of the human rights of sufferers.<sup>190</sup> This enabled the Thai government's pharmaceutical labs to manufacture a generic equivalent of the ARV at a fraction of the annual 1,800 dollars<sup>191</sup> per patient originally charged by the pharmaceutical company.<sup>192</sup> Unfortunately, Pfizer, the largest pharmaceutical company in the world, still rejects the idea of offering lower prices in developing countries and instead prefers to respond to public pressure by donating several drugs to treatment programs in select countries.<sup>193</sup> Although, these donations are helpful, they are unsustainable and do not provide a viable solution to the lack of access concerns.<sup>194</sup> Pharmaceutical companies should attempt to improve developing country access to essential pharmaceuticals without such government or activist threats. One example, in December 2003, pharmaceutical companies GlaxoSmithKline (GSK) and Boehringer Ingelheim allowed generic manufacturing firms to provide generic versions of their ARVs to South African patients.<sup>195</sup> As discussed above, many of these changes only came about after these companies were facing legal

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<sup>187</sup> 40 million pounds.

<sup>188</sup> Bailey, *supra* note 167.

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

<sup>191</sup> 900 pounds.

<sup>192</sup> Bailey, *supra* note 167.

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> *Id.*

action and widespread social disapproval, but anytime drug prices are reduced or drug access is increased, it is an improvement.<sup>196</sup>

Pharmaceutical companies should improve developing country access to essential medicines by issuing voluntary licenses.<sup>197</sup> This would provide a way around TRIPS as major pharmaceutical companies, as patent holders can bypass the TRIPS patent system by issuing voluntary licenses to allow other people to copy their drugs under certain conditions.<sup>198</sup> This would make it easier for these pharmaceutical companies' drugs to be produced generically with the permission of the company and would greatly improve access.<sup>199</sup> Pharmaceutical companies can work with developing countries rather than compounding the problem by imposing trade sanctions against developing countries. For example, in 2001, thirty-nine major pharmaceutical companies attempted to sue the South African government for passing a law not TRIPS compliant that allowed easy production and importation of generics.<sup>200</sup>

Following immense pressure from the South African government, the European Parliament and 300,000 people from over 130 countries that signed a petition against the action however, they were forced to back down. In an effort to put an end to the continuing row, one of the companies, GlaxoSmithKline, even granted a *voluntary license* to a major South African generics producer (Aspen), allowing them to share the rights to their drugs AZT, 3TC and the combination Combivir without charge. In return, Aspen had to promise to give 30 percent of their net sales to one or more non-governmental organi[z]ations fighting HIV and AIDS in South Africa, which they continue to do to this day.<sup>201</sup>

In addition to the pharmaceutical companies' duty to supply, there is also hope that generic drug manufacturing companies in developing countries will assume some of this responsibility to supply essential medicines and will invest more in R&D instead of simple reverse engineering.<sup>202</sup> This will allow developing country drug manufacturers to develop

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<sup>196</sup> *Id.*

<sup>197</sup> Boer, *supra* note 32 at 3.

<sup>198</sup> *Id.*

<sup>199</sup> *Id.*

<sup>200</sup> *Id.* at 3-4.

<sup>201</sup> *Id.* at 4 (emphasis added).

<sup>202</sup> *Id.* at 4.

original low cost medicines on their own.<sup>203</sup> Some of Indian companies (Cipla and Ranbaxy) have already begun assuming some of this responsibility by taking advantage of the fact that they are able to make a variety of different drugs from many competing pharmaceutical companies.<sup>204</sup> These companies have combined various ARVs into a one-a-day, easy-to-take fixed dose combinations that would be very difficult to manufacture in developed countries due to patent protection, but that are essential to HIV-AIDS treatment in developing countries due to their simplicity.<sup>205</sup> Since different drug companies hold the patents on each individual component of a drug, pharmaceutical patents hinder the development and availability of recommended fixed dosed combinations, which are extremely important in effective HIV-AIDS treatment.<sup>206</sup> Therefore, if drug manufacturing companies assume some of this duty to supply by creating low cost medicines on their own, the access to essential medicines in developing countries to individuals suffering from HIV-AIDS in developing countries would greatly improve.<sup>207</sup>

The importance of developing country access to second-line drugs is another reason why generic drug manufacturing companies should accept a duty to supply essential medicine to developing countries. Unfortunately, first-line drugs, whether brand name or generic, fail in approximately twenty percent of patients who take them.<sup>208</sup> Therefore, some patients need access to second-line drugs due to side effects or resistance.<sup>209</sup> As discussed above, while the Doha Declaration offers measures to protect the access of existing generics, much more needs to

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<sup>203</sup> Boer, *supra* note 32 at 4.

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> Hoen, *supra* note 1 at 2.

<sup>207</sup> Boer, *supra* note 32 at 4.

<sup>208</sup> Sabin Russell, *Rich Countries Urged to Boost AIDS Funding Developing Nations Expected to Need \$20 billion by 2007*, The Chronicle, available at <http://www.sfgate.com/cgi-bin/article.cgi?files=/c/a/2004/07/13/MN2B&KGJQ1.DTL> (last visited Apr. 10, 2005).

<sup>209</sup> This “will happen to nearly 10 to 20 percent of the patients, who will end up needing so-called second-line therapies that can cost as much as 20 times the price of the generics, threatening treatment programs with a sort of balloon payment down the road.” Russell, *supra* note 208.

be done to ensure the production and access to generic second-line drugs.<sup>210</sup> This is an enormous problem in developing countries because as the number of patients on first-line drugs grows and treatment failures occur, significant numbers of patients will require second-line brand name drugs that can cost over \$3,500 each year, which is approximately twenty times the cost of generic drugs.<sup>211</sup> Doctors Without Borders is hopeful that within the next few years, new formulations of cheap generic first-line drugs might have fewer side effects and have fewer instances of failure.<sup>212</sup> Further, they are hopeful that generic drug manufacturers will continue working on cheap versions of second-line drugs.<sup>213</sup> For example, “[o]ne promising prospect is to incorporate [the drug] Viread . . . made by Gilead Sciences Inc. . . . into lower-cost, second-line treatments for poor [developing] countries.”<sup>214</sup> Gilead has been selling Viread to developing countries for only its cost of production (\$1.30 per day), but Gilead has now offered to sell Viread at 80 cents per day.<sup>215</sup> Despite the fact that the cost of Viread is higher than the price of some three-drug combinations, it demonstrates that cost of second-line drugs might not have to be as devastating to budgets as some fear.<sup>216</sup> However, if the Bush Administration succeeds in combating the production of these second-line generics through the use of trade agreements with individual countries, these countries will be precluded from using any low cost, second-line generic drug.<sup>217</sup> Although the responsibility does not fall solely on pharmaceutical and generic manufacturing companies, it is crucial to global health that these companies take additional steps

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<sup>210</sup> Hoen, *supra* note 1 at 5.

<sup>211</sup> Russell, *supra* note 208.

<sup>212</sup> *Id.*

<sup>213</sup> Doctors Without Borders began its treatment program with AIDS medications costing \$10,000 per year and then quickly shifted to lower-cost drugs once they appeared. They are hopeful that something similar will happen with costly second-line drugs. *Id.*

<sup>214</sup> *Id.* at 3.

<sup>215</sup> *Id.*

<sup>216</sup> *Id.*

<sup>217</sup> Russell, *supra* note 208.

to improve access to essential medicines whether by cutting prices, issuing voluntary licenses, developing fixed-dose combination drugs, or developing generic versions of second-line drugs.

### *B. Governmental Duty to Supply*

It is both pharmaceutical companies' and governments' duty to supply medicine for AIDS.<sup>218</sup> It has been suggested that a constitutional approach to international law should be considered.<sup>219</sup> The international community should recognize "the interlocking relationships of enforceable contractual and normative duties that have developed between states and their citizens and between sovereigns and other sovereigns."<sup>220</sup> This argument goes beyond the scope of this comment, but provides an interesting focus on global welfare and of a government's duty to provide access to essential medicines rather than focusing merely on the provisions of TRIPS.<sup>221</sup> AIDS is a global health concern as it has spread to 40 million victims throughout the world.<sup>222</sup> Although Africa has been hit the hardest, AIDS has infected India and all 31 provinces of China.<sup>223</sup> "Medicine without social justice is unacceptable."<sup>224</sup> Therefore, two developing countries, Costa Rica and Venezuela have required their governments to supply AIDS drugs.<sup>225</sup>

Although, it is not easy for governments to supply drugs, there are several alternatives that could be employed to improve access to essential medicines. As discussed above, one method of improving access to essential medicines is through compulsory licenses. To reiterate, the WTO Decision allows member countries to import generics from other countries under compulsory licenses if the member country was unable to manufacture drugs within their home

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<sup>218</sup> See generally Cann, *supra* note 46.

<sup>219</sup> Cann, *supra* note 46 at 758.

<sup>220</sup> *Id.*

<sup>221</sup> *Id.* at 761.

<sup>222</sup> Dhavan, *supra* note 8 at 2.

<sup>223</sup> *Id.* at 3.

<sup>224</sup> *Id.* at 4.

<sup>225</sup> *Id.* at 3.



country and was suffering from a serious health crisis.<sup>226</sup> For LDCs and developing countries with insufficient or no capacity to manufacture drugs, it is a necessity for their governments to import drugs.<sup>227</sup> Third world countries have only two ways to obtain medicine: to access cheap medicine from countries with sufficient manufacturing capabilities (like India) or to pay exorbitant monopoly prices.<sup>228</sup> For example, the Indian government could grant compulsory licenses to domestic manufacturers who could export medicines to LDCs to get around this problem, but that process can be extremely difficult, time-consuming, and complicated for governments to implement.<sup>229</sup> Despite the public health need, there are many political and practical reasons (including drug regulation, fear of trade sanctions, jeopardizing supply of aid and investment from wealthy countries, etc.) why many governments do not grant compulsory licenses.<sup>230</sup> Accordingly, one example of the reluctance of developing countries to issue compulsory license is that the Zambian government, which declared a state of national emergency in September 2004, has been the only government willing to grant a compulsory license for AIDS drugs still under patent based on the scale of its HIV-AIDS crisis.<sup>231</sup>

Additionally, wealthy developed country governments have a responsibility to help improve global health to essential medicines to developing countries by contributing to prevention, treatment, and support programs that improve access to essential medicines, whether they are generic or brand name. Wealthy developed country governments (including the U.S. and Western European countries) need to boost their

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<sup>226</sup> Boer, *supra* note 32 at 3.

<sup>227</sup> Dhavan, *supra* note 8 at 3.

<sup>228</sup> *Id.* at 3.

<sup>229</sup> Compulsory licenses also “have political implications as companies and countries that hold the original patents to the drugs are unlikely to want to invest in a nation that is copying their products.” Boer, *supra* note 32 at 3.

<sup>230</sup> “At present the WHO does run a very successful scheme to assess generic drugs on a global scale and ensure they are bioequivalent (i.e. the same) as their propriety [brand name] counterparts, but even [the WHO] stress[es] that they are not a regulatory or drug-safety body and should not be treated as such.” *Id.*

<sup>231</sup> *Id.*

support of the Global Fund to Fight AIDS, Tuberculosis, and Malaria.<sup>232</sup> A UNAIDS report released as the 15th International AIDS Conference estimated the cost of HIV prevention, drug treatment, and support of AIDS orphans in the developing world in 2005 at \$12 billion and this jumps to \$20 billion in 2007.<sup>233</sup>

Although, the U.S. initially led the world in contributions to the Global Fund, the Bush Administration seems to favor its own program, President's Emergency Program for AIDS Relief (PEPFAR), that assist only the 15 hardest-hit countries rather than the 128 countries that the Global Fund assists.<sup>234</sup> The French medical organization Doctors Without Borders<sup>235</sup> contends that the Bush Administration's policies are designed to squash generic AIDS drugs because these drugs are made by overseas companies that ignore Western patents and have lower labor expenses.<sup>236</sup> The Global Fund accepts and uses these generic medicines, but the U.S. refuses to do so whereas the majority of the drugs prescribed by Doctors Without Borders are generic copies costing \$140 to \$300 a year, compared with \$12,000 for brand-name equivalents.<sup>237</sup> For example, skeptics assert the Bush Administration's program that approves generic drugs only if the companies can prove the generics work the same as their patented counterparts, is just another barrier to

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<sup>232</sup> Russell, *supra* note 208 at 1.

<sup>233</sup> *Id.*

<sup>234</sup> Through PEPFAR, the U.S. will spend \$15 billion over 5 years for overseas AIDS programs, including \$9 billion in new spending for prevention, treatments and orphan care in those 15 countries and only \$1 billion for the Global Fund. In 2004, Congress raised the contribution to \$540 million after criticism. However, for 2005, although, it has been estimated that the U.S. should contribute \$1.2 billion to the Global Fund, this PEPFAR program has effectively frozen the U.S.'s contribution to \$200 million. *Id.*

<sup>235</sup> Currently, one of the most aggressive organizations in the world that provides generic antiretroviral drugs to patients. Treating over 13,000 people in 25 different countries.

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

keep generics out of their program.<sup>238</sup> No generic drug to date has been cleared by this “fast track” process.<sup>239</sup>

Further, developed country governments’ have a duty to provide support for the TRIPS flexibilities affirmed in the Doha Declaration. Unfortunately, in recent years, there has been a “systematic dismantling” of the Doha Declaration due to corporate and governmental undue influence.<sup>240</sup> This “systematic dismantling” has been caused by the lack of political support for the use of TRIPS flexibilities.<sup>241</sup> One example of this is reflected in the “TRIPS plus” provisions in bilateral trade agreements with the U.S., which effectively destroy the Doha Declaration’s intent to utilize these flexibilities.<sup>242</sup> Even the European Parliament is concerned with the dismantling of the Doha Declaration advanced “insidiously through US-initiated Free Trade Agreements.”<sup>243</sup> For example, the proposed Central American Free-Trade Agreement (CAFTA) between the U.S., five Central American nations, and the Dominican Republic “essentially grants pharmaceutical companies a monopoly on new drugs registered in member countries.”<sup>244</sup> CAFTA even goes further than TRIPS “by requiring member countries to compensate patent owners for ‘unreasonable delays’ in obtaining a patent or market approval of a patented product by extending the patent life.”<sup>245</sup> Developed countries play a big role in giving political support for these flexibilities.<sup>246</sup> For example, it has been recommended to the European Parliament that it ensure that the European Commission “provides strong political support to countries that use

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<sup>238</sup> *Id.*

<sup>239</sup> Russell, *supra* note 208 at 2.

<sup>240</sup> Hoen, *supra* note 1.

<sup>241</sup> *Id.* at 5.

<sup>242</sup> *Id.* at 4.

<sup>243</sup> *Id.* at 7.

<sup>244</sup> Jill Replegle, *Central American Trade Pact May Limit Access to Generics*, *The Lancet*, vol. 363, May 15, 2004, available at <http://www.thelancet.com> (last visited Apr. 10, 2005).

<sup>245</sup> *Id.*

<sup>246</sup> Hoen, *supra* note 1 at 7.

the TRIPS flexibilities and offers technical assistance.”<sup>247</sup> Further, the European Commission must ensure that the Indian government, with its new Indian patent policies, will be able to continue its production and exportation of generic versions of newer medicines.<sup>248</sup>

Another instance of misinterpretation and misapplication of the Doha Declaration leading to the “systematic dismantling” of the Doha Declaration was by Canada, which contrary to the purpose of the WTO’s Decision, Canada created a list of approved medicines that could be exported in generic form to developing countries.<sup>249</sup> This list of approved medicines allowed drug industry lobbyists to keep new medicines off the list of approved medicines.<sup>250</sup> This included Bayer’s pneumonia therapy drug (moxifloxacin) and certain fixed dose AIDS drug combinations which are recommended by the WHO and which are vital for treating AIDS in developing countries.<sup>251</sup>

Regretfully, these hollow measures are often hailed as great progress, and the public and parliamentarians are led to believe that access problems have been resolved and that affordable medicines will now become available and no further action is needed. Such an approach would be disastrous.<sup>252</sup>

As of January 1, 2005, the access to new drugs is expected to become even more difficult.<sup>253</sup> This is because starting in 2005 all new drugs may be subject to at least 20 years of patent protection in all countries excluding the LDCs and the non-WTO countries.<sup>254</sup> However, a major concern is India because it supplies the majority of the affordable ARVs essential for

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<sup>247</sup> *Id.*

<sup>248</sup> *Id.*

<sup>249</sup> *Id.*

<sup>250</sup> *Id.*

<sup>251</sup> *Id.*

<sup>252</sup> *Id.*

<sup>253</sup> January 1, 2005 is the date agreed upon for the full implementation of TRIPS by developing countries that have not yet granted patents to pharmaceutical products. Hoen, *supra* note 1 at 4-5.

<sup>254</sup> “Because TRIPS implementation will affect both producers in key manufacturing countries and countries that are dependent on these manufacturers for raw materials, prices will be kept high and new medicines will be made inaccessible for the majority of the population in developing and least developed countries. Generic producers will also be blocked from developing fixed dose combinations until the relevant patents on the individual components of the combinations expire. In other words, access to essential medicines could become dramatically more difficult in the coming years if no further action is taken.” *Id.* at 4.

AIDS treatment.<sup>255</sup> According to the WHO, a number of developing countries implementing HIV-AIDS treatment programs are concerned with the catastrophic effects to their own countries based solely on India's implementation of TRIPS.<sup>256</sup> Brazil and Thailand provide examples of other developing countries that had successfully implemented HIV-AIDS programs before January 1, 2005 because key drugs had not yet been patent protected and therefore, these countries were producing HIV-AIDS drugs locally at much lower costs.<sup>257</sup> However, based on these new restrictions and challenges imposed after January 1, 2005, it is crucial that developed and developing countries adhere to the flexibilities discussed in the TRIPS Agreement and affirmed in the Doha Declaration to provide access to developing countries.<sup>258</sup>

The implications for developing countries as a result of TRIPS restricting competition, increasing prices, and limiting access to essential medicines are critical. TRIPS should be amended to take into consideration developing country interests by eliminating pharmaceutical monopolies and promoting global health through the imposition of governmental and corporate duties to provide access to essential medicines. However, until TRIPS is amended to promote access for all, all member countries should keep the following suggestions in mind as developing countries attempt to comply with the January 1, 2005 WTO deadline for domestic adoption of TRIPS compliant patent laws in developing countries.

First, it is imperative that generic drug producing countries (like Brazil, Thailand, and India) realize the importance of the public health safeguards affirmed in the Doha Declaration and routinely make use of these compulsory licenses and government use provisions in order to allow the export of these medicines and to enable the generic competition to drive down the

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<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> *Id.*

<sup>258</sup> *Id.*

prices of these medicines.<sup>259</sup> Second, it is important for developing country manufacturers to set a policy that if a patent holder does not respond to production on reasonable commercial terms within a stipulated period, a compulsory license will be granted in that country.<sup>260</sup> Third, the developing country manufacturer should limit the patent holder's royalty because setting high royalties allows the patent holder to take money from the manufacturer without any real contribution to the manufacturing process.<sup>261</sup> Fourth, although the compulsory license will be predominately for the manufacturing countries' domestic market, it is crucial to allow export to developing countries and LDCs with insufficient or no capacity to manufacture drugs without the government being required to get the patent holder's permission to export.<sup>262</sup> Finally, developing countries should emphasize the importance of the basic initial requirements of granting patents including novelty, inventive step, and industrial application.<sup>263</sup> If these requirements are not met, too many patented drug monopolies will be created.<sup>264</sup> For example, combination drugs and compounds do not meet the requirement of inventive step; therefore they should not be worthy of patent protection.<sup>265</sup>

## V. CURRENT DOMESTIC PHARMACEUTICAL PROTECTION AND DEVELOPMENTS IN DEVELOPING COUNTRIES

### A. *Indian Pharmaceutical Patent Law and Recent Developments*

A number of countries produce generic drugs including Canada, Brazil, South Africa, China, and Singapore, but the biggest producer is India.<sup>266</sup> Indian companies not only produce the finished tablet form of generic drugs, but they also produce cheaper versions of the raw

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<sup>259</sup> Hoen, *supra* note 1 at 4.

<sup>260</sup> Dhavan, *supra* note 8 at 2.

<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> *Id.*

<sup>264</sup> *Id.*

<sup>265</sup> *Id.*

<sup>266</sup> Boer, *supra* note 32 at 2.

ingredients and chemicals to export to major pharmaceutical companies to use in their brand name drugs.<sup>267</sup> A number of developing countries also produce generic AIDS drugs including Brazil, which has a very large generic pharmaceutical industry that enables its government to provide free ARVs to everyone that needs them.<sup>268</sup> India also produces large volumes of ARVs for its own people and for export.<sup>269</sup> These thriving generic pharmaceutical industries in developing countries, especially India, have shown that the price fixed by pharmaceutical companies have nothing to do with the cost of production, but more to do with the power of these companies as monopolies.<sup>270</sup>

“On May 6, 1981, Indira Gandhi declared India’s policy when she said her ‘idea of a better world is one in which medical discoveries would be free from patent and there will be no profiteering from life and death.’”<sup>271</sup> India’s policy quickly changed between 1987 and 1994 when the WTO treaty was negotiated.<sup>272</sup> The Indian Parliamentary records reflected great concern with the “‘grave impact of the proposed patent . . . on the drug prices in the country’ and warned that the ‘primacy of public interests for the right of patent holders should be ensured.’”<sup>273</sup> India passed the First Patents Amendment Act in 1999, the Second Amendment Act in 2002, and the Third Amendment Bill of 2003, which did not contain any ameliorative amendments and which was passed without change or discussion due to the implicit threat of WTO retaliation for non-compliance.<sup>274</sup> From 1995 to 2004, many foreign pharmaceutical companies filed

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<sup>267</sup> *Id.*

<sup>268</sup> *Id.*

<sup>269</sup> *Id.*

<sup>270</sup> “Yusuf Hamied of CIPLA has declared that he can supply medicine for HIV to Sub-Saharan Africa, India and the rest of the world at affordable prices.” Dhavan, *supra* note 8 at 1.

<sup>271</sup> *Id.* at 2.

<sup>272</sup> *Id.*

<sup>273</sup> *Id.*

<sup>274</sup> *Id.*

anticipatory claims against generic manufacturers under the WTO's "mail box" procedure,<sup>275</sup> which would become full-fledged patents on January 1, 2005.<sup>276</sup>

Until the end of 2004, India had no regulations on patenting, which is one of the reasons generic drug manufacturing became such a large-scale industry.<sup>277</sup> However, as India was mandated to meet the January 1, 2005 deadline to comply with the TRIPS regime, some of the cheap, generic anti-AIDS drugs India is famed for could be a thing of the past due to the new Indian patent laws that will come into force.<sup>278</sup> By rushing to comply with the TRIPS deadline, some argue that India has turned its own domestic law upside down and has given greater credence to WTO deadlines than to democracy.<sup>279</sup>

The WTO treaty is not the only treaty that India has to comply with. It is also a signatory to the Universal Declaration of Human Rights (1948), the Civil and Political and Economic and Social Rights Covenants (1996) and a host of others. The Supreme Court decisions culminating in and following Vishaka's case (1997) have directly imported many human rights into the life and liberty provisions of Article 21, including the right to health. The WTO cannot over-ride these obligations.<sup>280</sup>

Fortunately, although most of the ARVs listed as essential treatments by the WHO did not become physically available until 1996 or later, they had been patented well before TRIPS was introduced in 1995, therefore they can continue to be produced by India legally.<sup>281</sup> For drugs patented after 1995, if the original drug producer had also filed for and had been granted a patent in India, as of January 1, 2005<sup>282</sup> all current production of that drug must stop and all

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<sup>275</sup> The mailbox provision was a transitory provision offered by the government from 1995 to 2005 to enable drug firms interested in getting a patent to stake their claim until a domestic patent law was in place.

<sup>276</sup> Dhavan, *supra* note 8.

<sup>277</sup> Boer, *supra* note 32 at 2.

<sup>278</sup> Ranjit Devraj, *Goodbye to Cheap Indian AIDS Drugs?*, Inter Press Service News Agency, Nov. 26, 2004, available at <http://www.ipsnews.net/interna.asp?idnews=26445> (last visited Apr. 10, 2005).

<sup>279</sup> Dhavan, *supra* note 8 at 2.

<sup>280</sup> *Id.*

<sup>281</sup> Boer, *supra* note 32 at 3.

<sup>282</sup> When India introduced its domestic TRIPS based patent laws.



future production would be illegal for 20 years.<sup>283</sup> Developing countries, like India, are not influenced by the same sources or factors as developed countries (powerful pharmaceutical lobbyists and international trade) when creating national patent laws.<sup>284</sup> Instead, India's patent laws have been influenced by protectionism.<sup>285</sup>

India adopted weak patent laws especially with respect to pharmaceuticals due to concerns about the future of India's pharmaceutical industry and domestic health concerns.<sup>286</sup> In response to TRIPS, as well as to disputes with the U.S. and the WTO, the Indian government adopted the 1999 Patents Amendment Act to comply with WTO recommendations.<sup>287</sup> This Act sought to provide stronger patent protection for foreign pharmaceuticals and to create stronger domestic research capabilities.<sup>288</sup> For example, an Indian company (Ranbaxy Lab, Inc.) signed a \$90 million dollar joint venture with Eli Lilly & Co. to collaborate for pharmaceutical research and development.<sup>289</sup> These Indian patent laws could allow the Indian pharmaceutical industry to modernize its pharmaceutical industry and compete with the developed world.<sup>290</sup>

Although India has historically been against international patent regimes, in March 2005, the Indian government seriously considered whether it should strengthen its domestic patent protection based on the current strength of its pharmaceutical and biotechnology industries.<sup>291</sup> In 2004, the Indian Parliament originally attempted to adopt domestic legislation to comply with TRIPS, but when parliamentary approval for a modified patent law system became impossible in

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<sup>283</sup> Combivir, which was patented after 1995, is one of the few drugs that are likely to be affected. Boer, *supra* note 32 at 3.

<sup>284</sup> Barnes, *supra* note 4 at 918.

<sup>285</sup> *Id.*

<sup>286</sup> *Id.* at 927.

<sup>287</sup> *Id.*

<sup>288</sup> *Id.*

<sup>289</sup> *Id.*

<sup>290</sup> Barnes, *supra* note 4 at 927.

<sup>291</sup> *Indian Parliament Approves Controversial Patent Bill*, International Centre for Trade and Sustainable Development, Bridges Weekly Trade News Digest, vol. 9, no.10, Mar. 23, 2005 [hereinafter *Indian*], available at <http://www.ictsd.org/weekly/05-03-23/story1/htm> (last visited Apr. 10, 2005).

December 2004, the Indian government introduced an ordinance to ensure TRIPS compliance in time for the deadline.<sup>292</sup> This patent ordinance was heavily criticized and opposed by civil society groups and the Indian parliament for going beyond the demands of TRIPS.<sup>293</sup> Further, it was argued that the patent ordinance failed to fully incorporate the public health flexibilities provided in TRIPS and the Decision, outlining the circumstances under which countries can export and import generic versions of drugs still under patent.<sup>294</sup>

Accordingly, on March 23, 2005, the Indian government passed a controversial patent law designed to replace the patent ordinance following heated debate between the global drug industry and Indian firms versus Indian generic manufacturers (Cipla) over the last few months.<sup>295</sup> NGOs argue that effective compulsory licensing procedures play an important role in reducing the price of drugs and in ensuring access to affordable medicines, however the new Indian patent law is not adequate.<sup>296</sup> The Indian Union Minister of Commerce and Industry argues that the Indian government included enough safeguards in the 2005 Patents Amendment Act to prevent drug price increases.<sup>297</sup> The Indian Union Minister of Commerce and Industry, Shri Kamal Nath in support of the new Indian patent law said:

The price of medicines will not shoot up due to patents, because of these strong safeguards, checks and balances. There are comprehensive provisions in the amended Act to deal with issues concerning the price and availability of medicines. These include provisions for compulsory licensing to ensure availability of products at reasonable price; parallel import of products; acquisition of patent rights by the government; revocation of patents in the public interest; and provisions to deal with emergency situations.<sup>298</sup>

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<sup>292</sup> An ordinance is a temporary executive decree not debated in the Indian parliament. *Indian*, *supra* note 291 at 1.

<sup>293</sup> *Id.*

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*

<sup>296</sup> *Id.*

<sup>297</sup> Shri Kamal Nath, *Enough Safeguards in Patents Act to Prevent Price Rise - Domestic Pharma Industry Interest Fully Protected*, Press Information Bureau Government of India Ministry of Commerce and Industry, Apr. 4, 2005, available at <http://www.pib.nic.in/release/rel> (last visited Apr. 10, 2005).

<sup>298</sup> Nath, *supra* note 299 at 1.

### *B. South African Pharmaceutical Patent Law and Recent Developments*

Unlike India's patent laws, which have been influenced by protectionism, South Africa's controversial patent laws have been influenced by the serious public health crisis in South Africa due to HIV-AIDS.<sup>299</sup> Therefore, in 1997, the South African Parliament passed the Medicines and Related Substances Control Act based on its public health crisis.<sup>300</sup> The Minister of Health was allowed to use the tools within this Act to override patent protections including parallel importing and compulsory licensing to provide access to pharmaceuticals.<sup>301</sup> The Act allowed the South African government to use compulsory licensing provided the drug was initially marketed by the patentee or with the patentee's consent and the drug does not have other restrictions.<sup>302</sup> In fact, the patent holder rights would be overruled if those patent rights prevented South African companies from domestically developing effective versions of the medicines.<sup>303</sup>

The [M]inister [of Health] may prescribe conditions for the supply of more affordable medicines . . . so as to protect the health of the public, and . . . may [allow the importation of medicine] which is imported by a person other than the person who is the holder of the [patent]. [T]he council may . . . issue . . . a license to manufacture or act as a wholesaler of or distribute . . . such medicine or medicinal device.<sup>304</sup>

However, in April 2001, the South African Parliament passed the South African Medicines and Medical Devices Regulated Authority Act (SAMMDRA).<sup>305</sup> Since SAMMDRA was passed, the South African government has not attempted to grant any compulsory licenses and therefore, the international community has lifted its intense pressure to strictly comply with

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<sup>299</sup> Barnes, *supra* note 4 at 927.

<sup>300</sup> *Id.* at 930.

<sup>301</sup> *Id.*

<sup>302</sup> A compulsory license allows a country to choose a domestic company to produce drugs protected by foreign patents and sell the drugs for less than the patent holder would charge. Parallel importing is "reselling goods that were first sold in another country." A country buys the drugs on the international market wherever the drugs are the cheapest and imports those drugs for its own people. *Id.*

<sup>303</sup> *Id.*

<sup>304</sup> *Id.* at 931.

<sup>305</sup> The SAMMDRA rescinded the Medicines and Related Substances Amendment Act. Barnes, *supra* note 4 at 932.

TRIPS.<sup>306</sup> Recently, some progress in solving the lack of access concerns of South Africa have been made due to reductions in drug prices and withdrawal of litigation.<sup>307</sup> For example, the pharmaceutical industry dropped its court case against South Africa and the U.S. government dropped its WTO dispute settlement proceeding against Brazil.<sup>308</sup>

## VI. PROPOSED SOLUTIONS AND CONSIDERATIONS FOR REFORM OF THE GLOBAL PHARMACEUTICAL PATENT PROTECTION SYSTEM UNDER TRIPS

The current system of global pharmaceutical patent protection under TRIPS needs to be amended or revised to consider more specifically the needs of developing countries. Some examples of possible solutions and considerations to improve access include:

- Reducing the Prices and Increasing the Access to Pharmaceuticals in Developing Countries<sup>309</sup>
- Recognizing the Importance and Value of Generic Competition in International Trade<sup>310</sup>
- Creating a Systematic Tiered Pricing Mechanism for Pharmaceuticals<sup>311</sup>
- In Granting Patent Protection, Emphasize Inventive Step and Novelty and Limit the Duration and Scope of Patent Protection in Developing Countries<sup>312</sup>
- Creating or Amending Domestic Patent Laws to Make Full Use of the Flexibilities (Public Health Safeguards) in TRIPS by Emphasizing Public Health Over Patent Rights (Preventing the Systematic Dismantling of the Doha Declaration)<sup>313</sup>
- Allowing Developing Countries Without the Ability to Manufacture Pharmaceuticals To More Easily Be Able to Import Them<sup>314</sup>

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<sup>306</sup> *Id.*

<sup>307</sup> *Pfizer*, *supra* note 181 at 3.

<sup>308</sup> *Id.*

<sup>309</sup> Mohga Kamal Smith, *Generic Competition Price and Access to Medicines- The Case of Antiretrovirals in Uganda*, Oxfam Briefing Paper, vol. 26, June 2002, available at [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/downloads/bp26\\_generic.pdf](http://www.oxfam.org.uk/what_we_do/issues/health/downloads/bp26_generic.pdf) (last visited Apr. 10, 2005).

<sup>310</sup> *Id.* at 8.

<sup>311</sup> *Id.* at 9.

<sup>312</sup> Dhavan, *supra* note 8 at 3.

<sup>313</sup> Brant, *supra* note 3 at 31.

<sup>314</sup> Smith, *supra* note 309 at 9; Brant, *supra* note 3 at 31.

- Eliminating Developed Country Strategies for Bullying of Developing Countries (i.e., elimination of trade sanctions, TRIPS plus provisions in bilateral or regional trade agreements, contingent technical assistance, etc.)<sup>315</sup>
- Creating an International Fund for Research, Subsidizing Pharmaceutical Costs, Improving Health Services, and Improving Delivery Systems<sup>316</sup>

Recently, developing countries have gained considerable power in the world of international trade. “The World Trade Organization’s ministerial conferences have demonstrated a considerable willingness on the part of developing countries to build alliances among themselves as a way of countering the [influence] of the rich [developed] countries during trade negotiations.”<sup>317</sup> The inequalities created within the WTO agreements gave an overwhelming amount of power to rich developed countries.<sup>318</sup> Developing countries must remedy the unfairness found in these WTO trade agreements by adopting stronger negotiating postures within the WTO trade talks.<sup>319</sup> Developed countries like the U.S. and the E.U. have to be prevented from imposing their individually created “agreements” on other less powerful members.<sup>320</sup> Therefore, developing countries have to build solid alliances among themselves focused on specific negotiating proposals in order to be effective in trade talks.<sup>321</sup> Although, it seems impossible for developing countries to counter the intense political and financial power of big developed countries, developing countries are gaining some power within the WTO. This new, strong posture of developing countries has gradually emerged from the WTO Seattle Ministerial Conference demonstrations and from the WTO Doha Ministerial Conference

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<sup>315</sup> Brant, *supra* note 3 at 31.

<sup>316</sup> Smith, *supra* note 309 at 3.

<sup>317</sup> Adriano Compolina Soares, *G20, G90, and G33: Challenges for Building a New Politics*, Terraviva (Yale Global Policy Forum), Jan.23, 2005, available at <http://www.globalpolicy.org/soecon/bwi-wto/2005/0123g20.htm> (last visited Apr. 10, 2005).

<sup>318</sup> *Id.*

<sup>319</sup> *Id.*

<sup>320</sup> *Id.*

<sup>321</sup> *Id.*

proposals offered by developing countries on access to medications, which led to the Doha Declaration.<sup>322</sup>

While considerable progress has been made in including developing countries like Brazil and India in the decision-making nucleus of the WTO, a series of new challenges have emerged from this new developing country power dynamic.<sup>323</sup> Although the involvement of developing countries in the decision-making process is a clear improvement, the exclusion of other developing countries is unacceptable.<sup>324</sup> It is crucial not to create a WTO decision-making process, where the decisions are primarily made in small group alliances, whether developed or developing countries.<sup>325</sup> Encouraging these small alliances between member countries ultimately encourages the exclusion of certain other member countries.<sup>326</sup> Therefore, it is important to keep the decision-making process open to all member countries to create an international trade system based on democratic form and transparency.<sup>327</sup> In order for the developing country power dynamics emerging from the WTO Cancun Ministerial Conference to be transformed into an opportunity for fairer international trade rules and an opportunity for developing countries to succeed in counterbalancing the dominance of the developed countries, the dialogue within and between the groups of developing countries must continue to be deepened.<sup>328</sup>

## VII. CONCLUSION

Few of the victims of poverty-related diseases have heard of the WTO. Fewer still have had an opportunity to engage in debate over the implications of its rules for their welfare. Yet world trade laws have profound implications for developing countries –and nowhere more so than in the area of patents and public health. Governments in all developing [countries] are currently implementing sweeping changes in order to bring national legislation in line with WTO obligations [under TRIPS]. [Developing countries are doing this to avoid] threats of trade sanctions initiated by [developed countries, primarily the] US government acting on behalf of

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<sup>322</sup> *Id.*

<sup>323</sup> Soares, *supra* note 317 at 2.

<sup>324</sup> *Id.*

<sup>325</sup> *Id.*

<sup>326</sup> *Id.*

<sup>327</sup> *Id.*

<sup>328</sup> *Id.*

corporations [including pharmaceutical companies,] which stand to gain significant increases in their profits as a result of the new [patent] regime [being strictly enforced in developing countries].<sup>329</sup>

Between 2000 and 2020, it is estimated that sixty-eight million people will die from HIV-AIDS in the most affected countries.<sup>330</sup> Further, adult HIV-AIDS infection rates have escalated to 20.1% in South Africa and 37.5% in Botswana.<sup>331</sup> The HIV-AIDS epidemic continues to consume China, Indonesia, Central Asia, the Baltic States, and North Africa.<sup>332</sup> Since the adoption of TRIPS in 1994, slight improvements have been made in the global pharmaceutical patent system through the participation of the member countries in the WTO, the recognition by governments of the importance of the public health of its citizens and global public health, and the gradual flexibility of pharmaceutical companies in finding a solution to the HIV-AIDS crisis.<sup>333</sup>

TRIPS should be amended or reformed to consider the needs of developing countries. The implicit and explicit exceptions contained in TRIPS Article 8, 27, 30, 31, and 73, the Doha Declaration, and the Decision have all attempted to clarify the power of individual countries to protect the public health of their citizens. In reality, these safeguards are not enough. The arguments developed countries offer for the imposition of stringent patent protection in developing countries do not outweigh the potential harm created by allowing pharmaceutical companies to have monopolies that limit access to essential medicines. Pharmaceutical companies, generic drug manufacturers, and governments all have a duty to improve the access of developing countries to drugs including combination and second-line generic drugs. The current domestic pharmaceutical protection of patents in developing countries including India

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<sup>329</sup> *Cut the Cost*, *supra* note 18 at 18.

<sup>330</sup> Cann, *supra* note 46 at 757.

<sup>331</sup> *Id.*

<sup>332</sup> *Id.*

<sup>333</sup> *See Generally* Cann, *supra* note 46.

and South Africa is emerging with the January 1, 2005 TRIPS compliance mandate. Some possible solutions to improve access to drugs in developing countries are allowing generic competition, creating a tiered pricing mechanism to reduce prices, and providing political support for utilizing the public health safeguards contained in TRIPS. Unfortunately, AIDS and other infectious diseases are only some of the numerous problems facing developing countries today. Developing countries also lack the infrastructure and public health systems necessary to implement widespread disease treatment programs. Developed and developing countries should work together to develop an international pharmaceutical patent system that truly promotes global public health by providing equal access to all.